

June 10, 2005

From: Clune, Bridget [JNJIE]
To: Flett, Magnus [DPYGB]; Kalra, Vishnu [DPYGB]
Sent: 6/10/2005 10:00:30 AM
Subject: FW: ASR revised today

Hi Guys,
I am quite concerned
have been technique
so or is this phenome
Can we get together
Regards,
Bridget.

From: Clune, Bridget [JNJIE]
To: Flett, Magnus [DPYGB]; Kalra, Vishnu [DPYGB]
Sent: 6/10/2005 10:00:30 AM
Subject: FW: ASR revised today

Hi Guys,

I am quite concerned about our failure rate, I have had report from Emad Middle East, and Jose in Spain. All of these reports have been technique related, and the failure was in the seating of the cup. Have we had a history of failures over the last year or so or is this phenomenon related to the wider Roll-out?

We have done a few revisions now - am a little concerned that our number is growing. How is the rate globally?

I have not had official response for any retrieval we have sent to Hamburg. Only verbal on the one of Dr Zicat and Rogers

Regards

Jen

-----Original Message-----

From: Debbie Wilks [mailto:dcwilks@ozemail.com.au]

Sent: Thursday, 9 June 2005 9:55 PM

To: Babidge, Jenny [DPYAU]

Cc: Troy Collins; Mark Gibson; Loughlin, Marie [DPYAU]

Subject: ASR revised today

Hi Jen,

Just letting you know an ASR was revised today by Dr Zicat at the Mater Hospital. The original procedure was performed on the 21st October 2004 - implants used a 54 cup with a 47 head implanted with Endurance cement. The patient was revised due to increasing pain and presence of a gait. I spoke with Dr Zicat after the procedure and both implants were not loose but there was evidence of synovitis. The ASR cup was left insitu and the stem implanted was S-ROM. He has sent the sample for analysis to Dr Walsh at the POW lab as he feels he does not receive adequate feedback from the retrieved implants he has sent back to Depuy.

He will keep us informed of results he receives from Dr Walsh.

Regards,
Debbie.

Ex. 629

PROTECTED DOCUMENT. DOCUMENT SUBJECT TO PROTECTIVE ORDER.

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June 26, 2007

ECO-210520213471

SOP-1-21-Rev-56-App-A

DEPUY INTERNATIONAL
RESEARCH AND DEVELOPMENT REPORT

REPORT NO: RDR 091_07	PROJECT NO: A432
TITLE: ASR wear study of 63mm diameter bearings to 5M cycles.	
DESCRIPTION OF TEST PARTS OR MATERIALS:	

PASS/FAIL ACCEPTANCE CRITERIA:

The acceptance criteria was set such that ASR should wear at a similar or lower rate than the Ultamet 36mm bearings.

SUMMARY/ ABSTRACT:

Total mean volumetric wear of the ASR bearings over 5M cycles was 2.52mm^3 , and 0.15mm^3 for the ultamet implants. Mean bedding in wear measured from 0 to 1.5M cycles, for ASR and Ultamet bearings was 1.96mm^3 and 0.11mm^3 respectively, while steady state wear from 1.5M to 5M cycles for ASR and Ultamet bearings was 0.24mm^3 and 0.02mm^3 respectively. These results are presented graphically in Figure 1, Figure 2 and Figure 3 on the following pages.

wear of the ASR 39mm at 5M cycles is 4.0mm^3 and for the 28mm Ultima is 6.0mm^3 . The wear levels for 63mm ASR therefore fall below the wear levels of both 30mm ASR and 28mm Ultima (Figure 1). 30mm ASR

The current results for ASR do not meet the set acceptance criteria for this test.

ASSOCIATED FILES: WR671E. Full results in:
L:\Applied_Research\test_dir_struct\lab_documentation\Work_requests\results\WR671 ASR IDE 510k simulator test

AUTHOR	Name	Signature	Date
	M Hadley		
VERIFICATION			
APPROVAL	Approved for DHF use Yes/No		
If not approved for DHF state reasons			

Circulation: M Stewart; B Nofiz (Warsaw)

RDR 091_07

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M. Hadley 26 June 2007

SOP 1-21 rev 6, appendix A

M. Hadley 26 June 2007

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Potential solutions

- a. Significantly redesign the ASR cup to reduce lateralisation and remove the introducer groove. Potentially release as an alternative cup for patients likely to have high cup angles.
- b. Partially redesign the ASR cup to remove the groove
- c. Improve method used to align the acetabular component, surgeon training and/or instruments.
- d. Optimise groove geometry to reduce effect on wear (increase rim radius etc)
- e. Update surgical technique and avoid implant or instrument redesign

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May 2, 2008

From: Berman, Paul [DPYUS]
To: Hirsch, Jeremiah [DPYUS]
Sent: 5/2/2008 8:39:09 PM
Subject: Re: ASR Clinical Data

From: Berman, Paul [DPYUS]
To: Hirsch, Jeremiah [DPYUS]
Sent: 5/2/2008 8:39:09 PM
Subject: Re: ASR Clinical Data

Not sure it says but the assumption will be our internal lock ring. We will ultimately need a cup redesign but the short term action is manage perceptions.

----- Original Message -----

From: Berman, Paul [DPYUS]
To: Hirsch, Jeremiah [DPYUS]; Rhee, Michael [DPYUS]
Sent: Fri May 02 16:22:25 2008
Subject: Fw: ASR Clinical Data

Fyi guys.

Sent from my BlackBerry Wireless Handheld

----- Original Message -----

From: Flett, Magnus [DPYGB]
To: Berman, Paul [DPYUS]
Sent: Fri May 02 16:15:34 2008
Subject: Fw: ASR Clinical Data

PB, As we discussed today
Magnus Flett
Group Product Manager - Hips

Mobile Telephone +44 7789 924390

DePuy International Limited
Registered Office: St. Anthony's Road, Leeds, LS11 8DT, England
Registered in England No. 3319712

----- Original Message -----

From: Isaac, Graham [DPYGB]
To: Ekdahl, Andrew [DPYUS]; Camino, Tom [DPYUS]
Cc: Farrar, Richard [DPYGB]; Flett, Magnus [DPYGB]
Sent: Wed Apr 30 14:11:45 2008
Subject: ASR Clinical Data

Guys,

Yesterday we were given some clinical data which compares metal ion levels between BHR and ASR. In essence this shows that under certain conditions ASR is susceptible to extreme metal ion levels, whereas in the hands of the same surgeon BHR does not have the same problems. The difference is most pronounced in females and seems to be related to the use of small cups. I think this data has a bearing on the urgency of updating ASR. I believe that this data will appear in the journals in 2 parts in 6 month and 12 months and has the potential to seriously affect our business. We need to discuss this at the earliest possible opportunity as I believe it means that we need to start any ASR upgrade sooner than our previous plans had suggested. Is there any opportunity to discuss this tomorrow?

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November 7, 2008

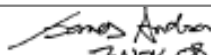
Project No: A539
Project Description: ASR II

DESIGN HISTORY FILE



Project cancellation

The project was taken to point of Phase I review. In light of new literature, the business case for the project could no longer be justified and it was decided to halt development of the ASR II / ALPHA cup.


7 Nov 08
James Anderson
Senior Bioengineer

Created by: janders23
Created on: 07 Nov 08

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Ex. 884

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From: Flett, Magnus [DPYGB]
 To: Denzer, Bernard [DPYUS]
 CC: Berman, Paul [DPYUS]; Finnegan, Paul [DPYIE]; Edgar, Derek [DPYUS]
 Sent: 9/17/2009 9:28:12 PM
 Subject: RE: ASR Feedback needed

Bernie,

1. Get out of ASR XL and ASR immediately
 - a. Best Case = 80% customer retained to Pinnacle
 - b. Worst Case = 60% customer retained to Pinnacle
 - c. Expectations = 70% customer retained to Pinnacle
2. Get out of ASR XL and ASR within 6 months
 - a. Best Case = 90% customer retained to Pinnacle
 - b. Worst Case = 70% customer retained to Pinnacle
 - c. Expectations = 80% customer retained to Pinnacle
3. Get out of ASR XL within 6 months but keep it around for just a few key surgeons who are big cutters
 - a. Best Case = 95% customer retained to Pinnacle
 - b. Worst Case = 80% customer retained to Pinnacle
 - c. Expectations = 90% customer retained to Pinnacle

I've included the market by market assessment of the top markets we made previously. We had no assumption on timing in that guess, but did include the withdrawal of both ASR and ASR XL (somewhere between 1 and 2 above), it totaled \$8.8M loss, you could double this to about \$15M to take account of all markets in international. So I suggest that 2 above should approx equal that amount

We can talk tomorrow

Magnus

4. Get out of ASR XL immediately
 - a. Best Case = XX% customer retained to Pinnacle
 - b. Worst Case = XX% customer retained to Pinnacle
 - c. Expectations = XX% customer retained to Pinnacle
5. Get out of ASR XL in 6 months
 - a. Best Case = XX% customer retained to Pinnacle

Ex. 753